K011336

JUN 12 2001

510(K) Summary

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1.	Submitter: Address: Phone: Fax: Contact:	Churchill Medical Systems, Inc. 87 Venture Drive Dover, NH 03820 603-743-5988 603-743-6328 Keith Paluch (Consultant)
2.	Device Name: Trade Name: Classification Name:	Primary Solution Set with Universal spike, Injection Site and Male Luer Lock I.V. Administration Set Set, Administration, Intravascular
3.	Classification:	Class II, General Hospital 80 FPA
4.	Predicate Device:	Excel I.V. Administration Set (K963659)
5.	Device Description:	The device consists of a universal vented or unvented spike with drip chamber, PVC tubing, roller clamp, Y-needle injection site and male luer lock connector.
6.	Intended Use:	This device is used to administer medical fluids from a container to patients vascular system through a catheter inserted into a vein.
7.	Performance Summary:	This device is manufactured and tested in accordance with physical, chemical and biological specification conforming to the applicable requirements set forth in ISO 10993, USPXX111, ISO 11607-1, ISO 11135, USP Pyrogenicity test requirements as well as documented internal requirements for physical testing.
8.	Conclusion:	This device is simple and shares similar technical characteristics to many I.V. administration sets currently available in the marketplace. Specifically, this device performs similarly to the predicate device, referred to as Excel I.V. Administration set (K963659). Testing summary results confirm this device to be safe and effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 2 2001

Mr. Kevin Paluch
General Manager
Churchill Medical Systems, Incorporated
87 Venture Drive
Dover, New Hampshire 03820

Re: K011336
Trade/Device Name: Primary Solution Set with Universal Spike, Injection Site
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA
Dated: April 30, 2001
Received: May 2, 2001

Dear Mr. Paluch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General hospital Devcies
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 011336

510(k) number K011336

Device Name: Primary Solution Set with Universal Spike and Male Luer Lock.

Indications For Use: Administer medical fluids from vented or unvented bags and bottle containers using head pressure to generate gravity flow.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use___
(Per 21CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011336